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| 10/720,050 | 11/19/2003 | Michael Yeadon | 01-1346 | 3489 |
| 28519 | 7590 | 08/27/2009 | | |
| MICHAEL P. MORRIS | | | EXAMINER | |
| BOEHRINGER INGELHEIM USA CORPORATION | | | CHONG, YONG SOO | |
| 900 RIDGEBURY RD | | | | |
| P O BOX 368 | | | ART UNIT | PAPER NUMBER |
| RIDGEFIELD, CT 06877-0368 | | | 1617 | |
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| | | | 08/27/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/720,050 | YEADON, MICHAEL | |
| | Examiner | Art Unit | |
| | Yong S. Chong | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 May 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 5,11-19,25 and 32 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4, 6-10, 20-24, 26-31, 33-34 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 5/14/08.

Claim(s) 1-34 are pending. Claim(s) 1 has been amended. Claim(s) 5, 11-19, 25, 32 have been withdrawn. Claim(s) 1-4, 6-10, 20-24, 26-31, 33-34 are examined herein.

Applicant's amendments have rendered the 112 rejection of the last Office Action moot, therefore hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection have been fully considered but found not persuasive. The 103(a) rejection of the last Office Action is maintained for reasons of record and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1, 2-4 (in part), 6-10, 20-22, 23-24 (in part), 26-31, 33-34 are rejected under 35 U.S.C. 103(a) as being obvious over Banerjee et al. (US Patent Application 2002/0151598 A1).

The instant claims are directed to a composition comprising pramipexole (dopamine D2-receptor agonist) and tiotropium of formula 1.1.1 (anti-cholinergic agent).

Banerjee et al. teach the treatment, prevention, or amelioration of bronchoconstrictive disorders (abstract). In a specific embodiment, a dopamine D2-receptor agonist and an anticholinergic agent is administered in combination with formoterol (paragraph 0076). A preferred dopamine D2-receptor agonist is pramipexole (paragraph 0078) and a preferred anticholinergic agent is tiotropium bromide at a concentration of 5 μ g/mL to 5 mg/mL (paragraph 0080). The teaching of tiotropium bromide meets the structural limitations found in claims 6-10, 26-30, and 33.

Pharmaceutically acceptable derivatives of a compound used herein include salts, such as hydrochlorides (paragraph 0029). The methods involve administering an effective amount of a pharmaceutical composition provided herein to a subject in need of such treatment (paragraph 0014). It is understood that the compounds for use in the compositions and methods provided herein may contain chiral centers. Such chiral centers may be either the (R) or (S) configuration, or may be a mixture thereof (paragraph 0033). The compositions are intended for administration as a nebulized aerosol (abstract). Examples of pharmaceutical packing materials include inhalers

(paragraph 0088) for example propellant-based metered dose inhalers and dry powder inhalers (paragraph 0040).

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

However, Banerjee et al. fail to disclose a composition comprising the specific combination of pramipexole and tiotropium.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have specifically combined pramipexole and tiotropium in the composition disclosed by Banerjee et al.

A person of ordinary skill in the art would have been motivated to have specifically combined pramipexole and tiotropium in the composition disclosed by Banerjee et al. because: (1) Banerjee et al. disclose a specific embodiment comprising a dopamine D2-receptor agonist and an anticholinergic agent in combination with formoterol; (2) Banerjee et al. disclose pramipexole as a preferred dopamine D2-receptor agonist; and (3) Banerjee et al. disclose tiotropium as a preferred anticholinergic agent. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating bronchoconstrictive disorders by administering a composition comprising pramipexole and tiotropium as taught by Banerjee et al.

Response to Arguments

Applicant argues that the teachings of Banerjee et al. used in the rejection does not have support to the provisional application filed on 4/17/2001, therefore disqualifying it as a prior art reference.

This is not persuasive because it is Applicant's burden to show that there is no support back to the provisional application filed on 4/17/2001. In the absence of any evidence, the obviousness rejection is maintained over the Banerjee et al. reference.

Applicant argues that does not suggest compositions wherein "the active agent consists of (I) a dopamine D2-receptor agonist, and (II) an anti-cholinergic agent" as recited by the newly amended claims, since Banerjee teaches that the inclusion of the beta2-adrenoreceptor agonist is a main characterizing feature of the Banerjee invention.

This is not persuasive because the instant claims do not preclude the inclusion of beta2-adrenoreceptor agonist as taught by Banerjee et al. Applicant is reminded that the instant claims clearly recite “a composition comprising,” which uses the open transitional phrase “comprising.”

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is
(571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1617

YSC